



**U.S. Department of Justice**

***Leah B. Foley***  
*United States Attorney*  
*District of Massachusetts*

*Main Reception: (617) 748-3100*

*John Joseph Moakley United States Courthouse*  
*1 Courthouse Way*  
*Suite 9200*  
*Boston, Massachusetts 02210*

February 28, 2025

George W. Vien, Esq.  
Michelle R. Pascucci, Esq.  
Emma Notis-McConarty, Esq.  
Donnelly, Conroy, and Gelhaar LLP  
260 Franklin Street, Suite 1600  
Boston, MA 02110

Re: *United States v. Mohammad Hossein Maleknia*  
Criminal No. 23-10094-PBS

Dear Counsel:

The United States Attorney for the District of Massachusetts (the "U.S. Attorney") and your client, Mohammad Hossein Maleknia ("Defendant"), agree as follows, pursuant to Federal Rule of Criminal Procedure ("Rule") 11(c)(1)(B):

1. Change of Plea

As soon as practicable, Defendant will plead guilty to Counts Five and Six of the Indictment: introduction of misbranded medical devices into interstate commerce with the intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). Defendant admits that Defendant committed the crimes specified in these counts and is in fact guilty of each one. The U.S. Attorney agrees to dismiss Counts One through Four of the Indictment following the imposition of sentence at Defendant's sentencing hearing.

2. Penalties

Defendant faces the following maximum penalties on each count: incarceration for three years; supervised release for one year; a fine of \$10,000; and a mandatory special assessment of \$100.

### 3. Sentencing Guidelines

The U.S. Attorney agrees, based on the following calculation, that Defendant's total offense level under the Guidelines is 31:

- a) Defendant's base offense level is 6 (USSG §§ 2N2.1(c), 2B1.1(a)(1));
- b) Defendant's offense level is increased by 20 because the loss attributable to the offense is more than \$9,500,000 but not more than \$25,000,000 (USSG § 2B1.1(b)(1)(K));
- c) Defendant's offense level is increased by 2 because the offense involved 10 or more victims (USSG § 2B1.1(b)(2)(A)(i));
- d) Defendant's offense level is increased by 2 because the offense involved the conscious or reckless risk of death or serious bodily injury (USSG § 2B1.1(b)(16)(A));
- e) Defendant's offense level is increased by 4 based on Defendant's role in the offense (§ 3B1.1(a)); and
- f) Defendant's offense level is decreased by 3 because Defendant has accepted responsibility for Defendant's crimes (USSG § 3E1.1).

Defendant reserves the right to argue, based on the following calculation, that Defendant's total offense level under the Guidelines is 2:

- a) Defendant's base offense level is 6 (USSG § 2N2.1(a));
- b) Defendant's offense level is decreased by 2 because Defendant has accepted responsibility for Defendant's crimes (USSG § 3E1.1); and
- c) Defendant's offense level is decreased by 2 because Defendant has zero criminal history points and otherwise meets the criteria for the adjustment under USSG § 4C1.1.

Defendant understands that the Court is not required to follow either of these calculations or even to sentence Defendant within the Guidelines and that Defendant may not withdraw Defendant's guilty plea if Defendant disagrees with how the Court calculates the Guidelines or with the sentence the Court imposes.

Defendant also understands that the government will object to any reduction in Defendant's sentence based on acceptance of responsibility if: (a) at sentencing, Defendant (directly or through counsel) indicates that Defendant does not fully accept responsibility for having engaged in the conduct underlying each of the elements of the crime to which Defendant is pleading guilty; or

(b) by the time of sentencing, Defendant has committed a new federal or state offense, or has in any way obstructed justice.

If, after signing this Agreement, Defendant's criminal history score or Criminal History Category is reduced, the U.S. Attorney reserves the right to seek an upward departure under the Guidelines.

Nothing in this Plea Agreement affects the U.S. Attorney's obligation to provide the Court and the U.S. Probation Office with accurate and complete information regarding this case.

4. Sentence Recommendation

The U.S. Attorney agrees to recommend the following sentence to the Court:

- a) incarceration for 12 months and one day;
- b) a fine of \$20,000;
- c) 12 months of supervised release; and
- d) a mandatory special assessment of \$200, which Defendant must pay to the Clerk of the Court by the date of sentencing.

Defendant agrees that all criminal monetary penalties, including special assessment, restitution, forfeiture, and/or fine imposed shall be due and payable immediately, and further agrees that any Court-ordered repayment schedule does not preclude further enforcement or collection by the United States.

5. Waiver of Appellate Rights and Challenges to Conviction or Sentence

Defendant has the right to challenge Defendant's conviction and sentence on "direct appeal." This means that Defendant has the right to ask a higher court (the "appeals court") to look at what happened in this case and, if the appeals court finds that the trial court or the parties made certain mistakes, overturn Defendant's conviction or sentence. Also, in some instances, Defendant has the right to file a separate civil lawsuit claiming that serious mistakes were made in this case and that Defendant's conviction or sentence should be overturned.

Defendant understands that Defendant has these rights, but now agrees to give them up. Specifically, Defendant agrees that:

- a) Defendant will not challenge Defendant's conviction on direct appeal or in any other proceeding, including in a separate civil lawsuit; and

- b) Defendant will not challenge Defendant's sentence, including any court orders related to forfeiture, restitution, fines or supervised release, on direct appeal or in any other proceeding, including in a separate civil lawsuit.

Defendant understands that, by agreeing to the above, Defendant is agreeing that Defendant's conviction and sentence will be final when the Court issues a written judgment after the sentencing hearing in this case. That is, after the Court issues a written judgment, Defendant will lose the right to appeal or otherwise challenge Defendant's conviction and sentence regardless of whether Defendant later changes Defendant's mind or finds new information that would have led Defendant not to agree to give up these rights in the first place.

Defendant is agreeing to give up these rights in exchange for concessions the U.S. Attorney is making in this Agreement.

The parties agree that, despite giving up these rights, Defendant keeps the right to later claim that Defendant's lawyer rendered ineffective assistance of counsel, or that the prosecutor or a member of law enforcement involved in the case engaged in misconduct serious enough to entitle Defendant to have Defendant's conviction or sentence overturned.

6. Waiver of Hyde Amendment Claim

Defendant is aware that the Court can award attorneys' fees and other litigation expenses to defendants in certain criminal cases. In exchange for the concessions the U.S. Attorney is making in this Agreement, Defendant waives any claim under the so-called "Hyde Amendment," 18 U.S.C. §3006A, that is based in whole or in part on the U.S. Attorney's agreement in Paragraph 1 to dismiss Counts One through Four of the Indictment.

7. Forfeiture

Defendant hereby waives and releases any claims Defendant may have to any vehicles, currency, or other personal property seized by the United States, or seized by any state or local law enforcement agency and turned over to the United States, during the investigation and prosecution of this case, and consents to the forfeiture of all such assets.

8. Civil Liability

This Plea Agreement does not affect any civil liability, including any tax liability, Defendant has incurred or may later incur due to Defendant's criminal conduct and guilty plea to the charges specified in Paragraph 1 of this Agreement.

9. Breach of Plea Agreement

Defendant understands that if Defendant breaches any provision of this Agreement, violates any condition of Defendant's pre-trial release or commits any crime following Defendant's execution of this Plea Agreement, Defendant cannot rely upon such conduct to

withdraw Defendant's guilty plea. Defendant's conduct, however, would give the U.S. Attorney the right to be released from the U.S. Attorney's commitments under this Agreement, to pursue any charges that were, or are to be, dismissed under this Agreement, and to use against Defendant any of Defendant's statements, and any information or materials Defendant provided to the government during investigation or prosecution of Defendant's case—even if the parties had entered any earlier written or oral agreements or understandings about this issue.

Defendant also understands that if Defendant breaches any provision of this Agreement or engages in any of the aforementioned conduct, Defendant thereby waives any defenses based on the statute of limitations, constitutional protections against pre-indictment delay, and the Speedy Trial Act, that Defendant otherwise may have had to any charges based on conduct occurring before the date of this Agreement.

10. Who is Bound by Plea Agreement

This Agreement is only between Defendant and the U.S. Attorney for the District of Massachusetts. It does not bind the Attorney General of the United States or any other federal, state, or local prosecuting authorities.

11. Modifications to Plea Agreement

This Agreement can be modified or supplemented only in a written memorandum signed by both parties, or through proceedings in open court.

\* \* \*

If this letter accurately reflects the agreement between the U.S. Attorney and Defendant, please have Defendant sign the Acknowledgment of Plea Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorneys Kelly Begg Lawrence, James D. Herbert, and Leslie A. Wright.

Sincerely,

LEAH B. FOLEY  
United States Attorney

By:



MACKENZIE A. QUEENIN  
Deputy Chief, Health Care Fraud Unit



KELLY BEGG LAWRENCE  
JAMES D. HERBERT  
LESLIE A. WRIGHT  
Assistant U.S. Attorneys



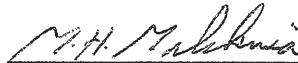
ACKNOWLEDGMENT OF PLEA AGREEMENT

I have read this letter and discussed it with my attorney. The letter accurately presents my agreement with the United States Attorney's Office for the District of Massachusetts. There are no unwritten agreements between me and the United States Attorney's Office, and no United States government official has made any unwritten promises or representations to me in connection with my guilty plea. I have received no prior offers to resolve this case.

I understand the crimes I am pleading guilty to, and the maximum penalties for those crimes. I have discussed the Sentencing Guidelines with my lawyer, and I understand the sentencing ranges that may apply.

I am satisfied with the legal representation my lawyer has given me, and we have had enough time to meet and discuss my case. We have discussed the charges against me, possible defenses I might have, the terms of this Agreement and whether I should go to trial.

I am entering into this Agreement freely and voluntarily and because I am in fact guilty of the offenses. I believe this Agreement is in my best interest.



Mohammad Hossein Maleknia  
Defendant

Date: 03 MAR 2025

I certify that Mohammad Hossein Maleknia has read this Agreement and that we have discussed what it means. I believe Mohammad Hossein Maleknia understands the Agreement and is entering into it freely, voluntarily, and knowingly. I also certify that the U.S. Attorney has not extended any other offers regarding a change of plea in this case.



George W. Vien  
Attorney for Defendant

Date: March 3, 2024